



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, DC 20460

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

September 23, 2019

Ian Murphy
Federal Registrations Manager
Bayer CropScience LP
2 T.W. Alexander Drive
P. O. Box 12014
RTP, NC 27709

Subject: Registration Review Label Mitigation for Metalaxyl and Trifloxystrobin
Product Name: Trilex Advanced 300
EPA Registration Number: 264-1069
Application Dates: 06/28/2018 and 09/10/2019
Decision Numbers: 555258 and 555168

Dear Mr. Murphy:

The Agency, in accordance with the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA), as amended, has completed reviewing all the information submitted with your application to support the Registration Review of the above referenced product in connection with Metalaxyl and Trifloxystrobin Interim Decisions, and has concluded that your submission is acceptable. The label referred to above, submitted in connection with registration under FIFRA, as amended, is acceptable.

Should you wish to add/retain a reference to the company's website on your label, then please be aware that the website becomes labeling under the Federal Insecticide Fungicide and Rodenticide Act and is subject to review by the Agency. If the website is false or misleading, the product would be misbranded and unlawful to sell or distribute under FIFRA section 12(a)(1)(E). 40 CFR 156.10(a)(5) list examples of statements EPA may consider false or misleading. In addition, regardless of whether a website is referenced on your product's label, claims made on the website may not substantially differ from those claims approved through the registration process. Therefore, should the Agency find or if it is brought to our attention that a website contains false or misleading statements or claims substantially differing from the EPA approved registration, the website will be referred to the EPA's Office of Enforcement and Compliance.

A copy of your label stamped "Accepted" is enclosed. Products shipped after 12 months from the date of this amendment must bear the new revised label. Your release for shipment of the product bearing the amended label constitutes acceptance of these conditions. If these conditions are not complied with, the registration will be subject to cancellation in accordance with FIFRA section 6.

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If you have any questions about this letter, please contact Srijana Shrestha by phone at 703-305-6471, or via email at Shrestha.srijana@epa.gov.

Sincerely,

A handwritten signature in blue ink, appearing to be "Linda Arrington", with a stylized flourish at the end.

Linda Arrington, Branch Chief
Risk Management and Implementation Branch 4
Pesticide Re-Evaluation Division
Office of Pesticide Programs

Enclosure

TRIFLOXYSTROBIN	GROUP	11	FUNGICIDE
TRIADIMENOL	GROUP	3	FUNGICIDE
METALAXYL	GROUP	4	FUNGICIDE

TRILEX[®] Advanced 300

ACTIVE INGREDIENTS:

Trifloxystrobin.....	8.55%
Triadimenol.....	4.27%
Metalaxyl.....	12.82%

OTHER INGREDIENTS.....74.36%

TOTAL100.00%

Contains 0.42 lb. triadimenol per gallon, 1.25 lb metalaxyl per gallon and 0.83 lb trifloxystrobin per gallon.

EPA Reg. No. 264-1069

EPA Est.

KEEP OUT OF REACH OF CHILDREN CAUTION

For MEDICAL And TRANSPORTATION Emergencies ONLY Call 24 Hours A Day 1-800-334-7577
For PRODUCT USE Information Call 1-866-99BAYER (1-866-992-2937)

Please refer to [back panel] [booklet] for additional precautionary statements and directions for use. [Note to reviewer: Location of additional precautionary statements and directions for use will vary between those listed, depending on container type/size.]

FIRST AID

IF SWALLOWED:	<ul style="list-style-type: none"> • Call a poison control center or doctor immediately for treatment advice. • Have person sip a glass of water if able to swallow. • Do not induce vomiting unless told to do so by a poison control center or doctor. • Do not give anything to an unconscious person.
IF IN EYES:	<ul style="list-style-type: none"> • Hold eye open and rinse slowly and gently with water for 15 to 20 minutes. Remove contact lenses, if present, after the first 5 minutes, then continue rinsing eye. • Call a poison control center or doctor for treatment advice.
IF ON SKIN:	<ul style="list-style-type: none"> • Take off contaminated clothing. • Rinse skin immediately with plenty of water for 15 to 20 minutes. • Call a poison control center or doctor for treatment advice.
IF INHALED:	<ul style="list-style-type: none"> • Move person to fresh air. • If person is not breathing, call 911 or an ambulance, then give artificial respiration, preferably mouth-to-mouth if possible. • Call a poison control center or doctor for treatment advice.

In case of emergency call toll free the Bayer CropScience Emergency Response Telephone No. 1-800-334-7577.
Have a product container or label with you when calling a poison control center or doctor, or going for treatment.

ACCEPTED

Sep 23, 2019

Under the Federal Insecticide, Fungicide
and Rodenticide Act as amended, for the
pesticide registered under
EPA Reg. No. 264-1069

PRECAUTIONARY STATEMENTS

HAZARDS TO HUMANS AND DOMESTIC ANIMALS

CAUTION

Harmful if swallowed, inhaled, or absorbed through skin. Causes moderate eye irritation. Avoid contact with skin, eyes, or clothing. Wash thoroughly with soap and water after handling. Remove contaminated clothing and wash before reuse.

PERSONAL PROTECTIVE EQUIPMENT (PPE):

Applicators and other handlers must wear: Long sleeved shirt and long pants, socks, shoes and chemical-resistant gloves made of any waterproof material. Chemical resistant materials include barrier laminate, butyl rubber ≥ 14 mils, neoprene rubber ≥ 14 mils, polyvinyl chloride (PVC) or viton ≥ 14 mils. Follow manufacturer's instructions for cleaning/maintaining PPE. If no such instructions for washables exist, use detergent and hot water. Keep and wash PPE separately from other laundry.

Engineering Controls: When handlers use closed systems in a manner that meets the requirements listed in the Worker Protection Standard (WPS) for agricultural pesticides [40 CFR 170.240(d) (4-6)], the handler PPE requirements may be reduced or modified as specified in the WPS.

USER SAFETY RECOMMENDATIONS:

Users should wash hands before eating, drinking, chewing gum, using tobacco or using the toilet. Users should remove clothing/PPE immediately if pesticide gets inside. Then wash thoroughly and put on clean clothing. Users should remove PPE immediately after handling the product. Wash the outside of gloves before removing. As soon as possible, wash thoroughly and change clothing.

ENVIRONMENTAL HAZARDS

This pesticide is toxic to fish and aquatic invertebrates. Applying this product when rain is not predicted for the next 24 hours will help reduce potential risk to aquatic invertebrates by reducing pesticide runoff from the treatment area into water bodies. Do not apply directly to water, or to areas where surface water is present or to intertidal areas below the mean high water mark. Do not contaminate water when disposing of equipment washwaters. Drift or run-off from treated areas is hazardous to fish and aquatic organisms in water adjacent to treated areas. Treated seed exposed on the soil surface may be hazardous to wildlife. Cover or collect seeds spilled during loading.

Groundwater Advisory: Metalaxyl is known to leach through soil into groundwater under certain conditions as a result of agricultural use. Use of this chemical in areas where soils are permeable, particularly where the water table is shallow, may result in groundwater contamination.

DIRECTIONS FOR USE

It is a violation of Federal law to use this product in a manner inconsistent with its labeling.

Do not apply this product in a way that will contact workers or other persons, either directly or through drift. Only protected handlers may be in the area during application. For any requirements specific to your State or Tribe, consult the State or Tribe agency responsible for pesticide regulation.

PRODUCT INFORMATION

TRILEX ADVANCED 300:

- provides seed and seedling protection against seed-borne fungi causing seed decay and soil-borne pathogens such as *Fusarium*, *Rhizoctonia*, *Pythium*, and *Thielaviopsis basicola* (suppression; for control add Baytan 30 to increase total amount of triadimenol between 0.021 and 0.062 pounds triadimenol per 100 pounds of seed).
- is a concentrated formulation especially formulated for application using standard slurry or mist-type commercial treatment equipment.

RESTRICTIONS

- Maximum usage when applying both metalaxyl- and mefenoxam-containing products to the same crop within the same season: Do not apply more than the maximum yearly total application rate for the active ingredient as stated on the label of the product containing the lowest yearly total on that crop.
- Do not use in hopper box, planter box, slurry box, or other farmer-applied applications. Consult a seed treatment specialist for proper guidelines in using TRILEX ADVANCED 300 to insure uniform coverage of seed, thus ensuring seed safety and best disease protection.

USE PRECAUTION

- Seed treated commercially or for sale must be dyed an unnatural color using an EPA approved dye before being sold.

ROTATIONAL CROP RESTRICTIONS

Areas planted with treated seed may be replanted immediately with any crop for which tolerances exist for trifloxystrobin, triadimenol, and metalaxyl. Do not plant any crop without trifloxystrobin, metalaxyl or triadimenol tolerance until 30 days after planting treated seed.

RESISTANCE MANAGEMENT RECOMMENDATION

For resistance management, please note that TRILEX ADVANCED 300 contains a Group 4 [Phenylamides class], a Group 11 [Quinone outside Inhibitors] and a Group 3 [DeMethylation Inhibitors] fungicide. Any fungal population may contain individuals naturally resistant to TRILEX ADVANCED 300 and other Group 4, 11, or 3 fungicides. A gradual or total loss of pest control may occur over time if these fungicides are used repeatedly in the same fields. Appropriate resistance-management strategies should be followed.

To delay fungicide resistance, take one or more of the following steps:

- Adopt an integrated disease management program for fungicide use that includes scouting, uses historical information related to pesticide use, and crop rotation, and which considers host plant resistance, impact of environmental conditions on disease development, disease thresholds, as well as cultural, biological and other chemical control practices.
- Monitor treated fungal populations for resistance development.
- Contact your local extension specialist or certified crop advisor for any additional pesticide resistance-management and/or IPM recommendations for specific crops and pathogens.
- For further information or to report suspected resistance contact Bayer CropScience at 1-866-99BAYER (1-866-992-2937). You can also contact your pesticide distributor or university extension specialist to report resistance.

SEED TREATMENT USES

Cotton

Apply TRILEX ADVANCED 300 at 1.6 fluid ounces per 100 pounds of seed.

LABELING OF TREATED SEED

Seed treated commercially or for sale with TRILEX ADVANCED 300 must be labeled in accordance with all applicable requirements of the Federal Seed Act. All bags containing treated seed must be labeled or tagged as follows:

- "This seed has been treated with trifloxystrobin, triadimenol, and metalaxyl.
- Do not use for feed, food or oil purposes.
- Store away from feed and food.
- Do not plant any crop without trifloxystrobin tolerances until 30 days after planting treated seed.
- Excess treated seed may be used for ethanol production only if (1) byproducts are not used for livestock feed and (2) no measurable residues of pesticide remain in ethanol by-products that are used in agronomic practice."

STORAGE AND DISPOSAL

Do not contaminate water, food or feed by storage and disposal.

Pesticide Storage: Store in a cool dry location. Do not store in direct hot sunlight. Do not store above 90°F for prolonged periods of time. After prolonged storage in intense cold, allow product to return to approximately 75°F before using.

Pesticide Disposal: Pesticide wastes are toxic. Improper disposal of excess pesticide, spray mixture, or rinsate is a violation of Federal Law. If these wastes cannot be disposed of by use according to label instructions, contact your State or Environmental Control Agency, or Hazardous Waste representative at the nearest EPA Regional Office for guidance.

Container Handling: Non-refillable container. Do not reuse or refill this container. Triple rinse or pressure rinse container (or equivalent) promptly after emptying.

Rigid Non-refillable containers small enough to shake (capacities equal to or less than 5 gallons).

Triple rinse as follows: Empty the remaining contents into application equipment or a mix tank and drain for 10 seconds after the flow begins to drip. Fill the container ¼ full with water and recap. Shake for 10 seconds. Pour rinsate into application equipment or a mix tank or store rinsate for later use or disposal. Drain for 10 seconds after the flow begins to drip. Repeat this procedure two more times.

Pressure rinse as follows: Empty the remaining contents into application equipment or a mix tank and continue to drain for 10 seconds after the flow begins to drip. Hold container upside down over application equipment or mix tank or collect rinsate for later use or disposal. Insert pressure rinsing nozzle in the side of the container, and rinse at about 40 PSI for at least 30 seconds. Drain for 10 seconds after the flow begins to drip.

Offer for recycling, if available. If not recycled then puncture and dispose of in a sanitary landfill, or by incineration, or, if allowed by state and local authorities by burning. If burned, stay out of smoke.

Rigid Non-refillable containers that are too large to shake (i.e., with capacities greater than 5 gallons or 50 lbs)

Non-refillable containers - Do not reuse or refill this container. After emptying product from container, either return container to Bayer CropScience per instructions from Bayer CropScience Customer Service Center (1-800-527-4781), or rinse and either recycle or dispose of the container as follows:

Bottom Discharge IBC (e.g. – Schuetz Caged IBC or Snyder Square Stackable)

Pressure rinsing the container before final disposal is the responsibility of the person disposing of the container. To pressure rinse the container before final disposal, empty the remaining contents from the IBC into application equipment or mix tank. Raise the bottom of the IBC by 1.5 inches on the side which is opposite of the bottom discharge valve to promote more complete product removal. Completely remove the top lid of the IBC. Use water pressurized to at least 40 PSI to rinse all interior portions. Continuously pump or drain rinsate into application equipment or rinsate collection system while pressure rinsing. Continue pressure rinsing for 2 minutes or until rinsate becomes clear. Replace the lid and close bottom valve.

Top Discharge IBC, Drums, Kegs (e.g. – Snyder 120 Next Gen, Bonar B120, Drums, and Kegs).

Triple rinsing the container before final disposal is the responsibility of the person disposing of the container. To triple rinse the container before final disposal, empty the remaining contents from this container into application equipment or mix tank. Fill the container at least 10 percent full with water. Agitate vigorously or recirculate water with the pump for 2 minutes. Rinse all interior surfaces. Pour or pump rinsate into application equipment or rinsate collection system. Repeat this procedure two more times.

Once container is rinsed, offer for recycling if available or puncture and dispose of in a sanitary landfill, or by incineration.

IMPORTANT: READ BEFORE USE

Read the entire Directions for Use, Conditions, Disclaimer of Warranties and Limitations of Liability before using this product. If terms are not acceptable, return the unopened product container at once. By using this product, user or buyer accepts the following Conditions, disclaimer of Warranties and Limitations of Liability.

Treatment of highly mechanically damaged seed, or seed of known low vigor and poor quality, may result in reduced germination and/or reduction of seed and seedling vigor. Treat and conduct germination tests on a small portion of seed before committing the total seed lot to a selected chemical treatment. Due to seed quality conditions beyond the control of Bayer CropScience, no claims are made to guarantee germination of carry-over seed.

CONDITIONS: The directions for use of this product are believed to be adequate and must be followed carefully. However, it is impossible to eliminate all risks associated with the use of this product. Crop injury, ineffectiveness or other unintended consequences may result because of such factors as weather conditions, presence of other materials, or the manner of use or application, all of which are beyond the control of Bayer CropScience. All such risks shall be assumed by the user or buyer.

DISCLAIMER OF WARRANTIES: TO THE EXTENT CONSISTENT WITH APPLICABLE LAW, BAYER CROPSCIENCE MAKES NO WARRANTIES, EXPRESS OR IMPLIED, OF MERCHANTABILITY OR OF FITNESS FOR A PARTICULAR PURPOSE OR OTHERWISE, THAT EXTEND BEYOND THE STATEMENTS MADE ON THIS LABEL. No agent of Bayer CropScience is authorized to make any warranties beyond those contained herein or to modify the warranties contained herein. TO THE EXTENT CONSISTENT WITH APPLICABLE LAW, BAYER CROPSCIENCE DISCLAIMS ANY LIABILITY WHATSOEVER FOR SPECIAL, INCIDENTAL OR CONSEQUENTIAL DAMAGES RESULTING FROM THE USE OR HANDLING OF THIS PRODUCT.

LIMITATIONS OF LIABILITY: TO THE EXTENT CONSISTENT WITH APPLICABLE LAW, THE EXCLUSIVE REMEDY OF THE USER OR BUYER FOR ANY AND ALL LOSSES, INJURIES OR DAMAGES RESULTING FROM THE USE OR HANDLING OF THIS PRODUCT, WHETHER IN CONTRACT, WARRANTY, TORT, NEGLIGENCE, STRICT LIABILITY OR OTHERWISE, SHALL NOT EXCEED THE PURCHASE PRICE PAID, OR AT BAYER CROPSCIENCE'S ELECTION, THE REPLACEMENT OF PRODUCT.

NET CONTENTS:

Trilex is a registered trademark of Bayer

Produced for



Bayer CropScience LP
800 N. Lindbergh Blvd.
St. Louis, MO 63167
1-866-99BAYER (1-866-992-2937)

TRILEX Advanced 300 Seed Applied System (PENDING) 06/02/2018, 06/26/2018, 09/03/2019